



Pneumococcal Vaccines

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Pneumococcal Vaccines Work Group Chair

Advisory Committee on Immunization Practices

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Pneumococcal Vaccines Work Group

- **ACIP Members**

- Katherine Poehling (Chair)
- Keipp Talbot
- Sarah Long

- **Ex Officio Members**

- Jeffrey Kelman (CMS)
- Lucia Lee (FDA)
- Tina Mongeau (FDA)
- Thomas Weiser (IHS)
- Kristina Lu (NIH)

- **CDC Lead**

- Miwako Kobayashi (NCIRD)

- **Liaison Representatives and Consultants**

- Lynn Fisher (AAFP)
- Mark Sawyer (AAP/COID)
- Jason Goldman (ACP)
- David Nace (AGS/AMDA)
- Emily Messerli (AIM)
- Oliver Baclic (NACI)
- Carol Baker (IDSA)
- William Schaffner (NFID)
- Virginia Caine (NMA)
- Monica Farley (VAMC/Emory)
- Keith Klugman (BMGF)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
- Cynthia Whitney (Emory)
- Richard Zimmerman (U. of Pittsburgh)

Pneumococcal Vaccines Work Group

- **CDC Contributors**

- Tamara Pilishvili (Respiratory Diseases Branch)
- Ryan Gierke (Respiratory Diseases Branch)
- Jennifer Farrar (Respiratory Diseases Branch)
- Penina Haber (Immunization Safety Office)
- Pedro Moro (Immunization Safety Office)
- Sarah Schillie (Immunization Services Division)
- Marc Fischer (Arctic Investigations Program)
- Jessica MacNeil (ACIP Secretariat)

- **GRADE/EtR consultants**

- Doug Campos-Outcalt
- Rebecca Morgan

Current and New Pneumococcal Vaccines

- Current
 - 23-valent pneumococcal polysaccharide vaccine (PPSV23), Merck
 - 13-valent pneumococcal conjugate vaccine (PCV13), Pfizer
- New
 - **20-valent pneumococcal conjugate vaccine (PCV20), Pfizer**
 - Licensed for use in adults aged ≥ 18 years on June 8th¹
 - **15-valent pneumococcal conjugate vaccine (PCV15), Merck**
 - BLA filed to FDA, licensure anticipated in July 2021²

1. <https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-prevnar-20tm-pfizers-pneumococcal-20-valent>

2. <https://www.merck.com/news/u-s-fda-accepts-for-priority-review-the-biologics-license-application-for-v114-mercks-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-18-years-of-age-and-older/>

Current Adult Pneumococcal Vaccine Recommendations

	19–64 years	≥65 years
None of the conditions listed below	No recommendation	PCV13* based on shared clinical decision making, PPSV23 for all
Chronic medical conditions† (CMC)	PPSV23	PCV13* based on shared clinical decision making, PPSV23 for all
Cochlear implant, CSF leak	Both PCV13* and PPSV23	Both PCV13* and PPSV23
Immunocompromising conditions	Both PCV13* and PPSV23, repeat PPSV23 after 5 years	Both PCV13* and PPSV23

PCV13: 13-valent pneumococcal conjugate vaccine

PPSV23: 23-valent pneumococcal polysaccharide vaccine

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking

<https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>

Current Adult Pneumococcal Vaccine Recommendations (simplified)

	19–64 years	≥65 years
None of the conditions listed below	No recommendation	PCV13* based on shared clinical decision making, PPSV23 for all
Chronic medical conditions† (CMC)	PPSV23	
Cochlear implant, CSF leak	PCV13-PPSV23 series	
Immunocompromising conditions		

PCV13: 13-valent pneumococcal conjugate vaccine

PPSV23: 23-valent pneumococcal polysaccharide vaccine

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking

<https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>

Guiding Principles Proposed by the Work Group

- Decisions on policy options should be supported by best-available evidence
- Simplification of pneumococcal vaccine recommendations, which might improve uptake
- Disparities in pneumococcal disease burden and vaccine coverage should be reduced
- Timely recommendations for each new vaccine should be made after FDA licensure

Overarching Policy Questions Under Consideration by the Work Group

- Should PCV15 be routinely recommended in adults aged ≥ 50 or ≥ 65 years?
- Should PCV15 be recommended in younger adults with underlying medical conditions?
- Should PCV20 be routinely recommended in adults aged ≥ 50 or ≥ 65 years?
- Should PCV20 be recommended in younger adults with underlying medical conditions?
- Should recommendations be made for PCV15 and PCV20 alone or in series with PPSV23?

Policy Options for Cost-Effectiveness Analysis

The following 8 strategies were compared to the current pneumococcal vaccine recommendations.

	Age 19–64 years with underlying conditions	All aged ≥ 65 years
Strategy a	PCV15	PCV15
Strategy b	PCV20	PCV20
Strategy c	PCV15+PPSV23	PCV15+PPSV23
Strategy d	PCV20+PPSV23	PCV20+PPSV23
	Age 19–49 years with underlying conditions	All aged ≥ 50 years
Strategy a	PCV15	PCV15
Strategy b	PCV20	PCV20
Strategy c	PCV15+PPSV23	PCV15+PPSV23
Strategy d	PCV20+PPSV23	PCV20+PPSV23

Policy Options for Cost-Effectiveness Analysis

After reviewing the results of the cost-effectiveness analysis and estimated public health impact from each policy option, the Work Group focused on **the following 4 options**.

	Age 19–64 years with underlying conditions	All aged ≥65 years
Strategy a	PCV15	PCV15
Strategy b	PCV20	PCV20
Strategy c	PCV15+PPSV23	PCV15+PPSV23
Strategy d	PCV20+PPSV23	PCV20+PPSV23
	Age 19–49 years with underlying conditions	All aged ≥50 years
Strategy a	PCV15	PCV15
Strategy b	PCV20	PCV20
Strategy c	PCV15+PPSV23	PCV15+PPSV23
Strategy d	PCV20+PPSV23	PCV20+PPSV23

Grading of Recommendations, Assessment, Development and Evaluation (GRADE)

■ **PCV15 and PCV20**

- New vaccines under consideration
- Licensure based on non-inferior immunogenicity compared to current vaccines (PCV13, PPSV23 for non-PCV13 serotypes)
- Currently no data on efficacy against clinical outcomes

■ **PCV13 and PPSV23**

- Data on efficacy/effectiveness against disease outcomes available

PCV13 and PPSV23 data reviewed for background,
GRADE based on PCV15 and PCV20 immunogenicity studies

Today's Pneumococcal Vaccines Session Outline

Introduction

Dr. Katherine Poehling
(ACIP, WG Chair)

Updates on epidemiology of pneumococcal disease in U.S. adults

Mr. Ryan Gierke
(CDC/NCIRD)

Cost effectiveness of PCV15 and PCV20 use in U.S. adults

Dr. Charles Stoecker
(Tulane)

GRADE for age-based PCV15 and PCV20 use in U.S. adults

Ms. Jennifer Farrar
(CDC/NCIRD)

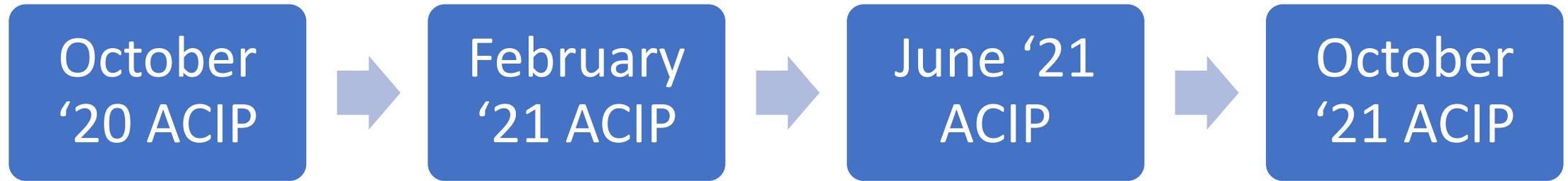
EtR summary of age-based PCV15 and PCV 20 use in U.S. adults

Dr. Miwako Kobayashi
(CDC/NCIRD)

Summary and Timeline

Dr. Miwako Kobayashi
(CDC/NCIRD)

Initial Proposed Timeline of ACIP Presentations



Presentation on:

- Epidemiology of current U.S. pneumococcal disease
- New vaccine products and summary of phase 3 study results
- Policy question(s) proposed by the WG

Presentation on:

- Cost-effectiveness analysis
- EtR/GRADE

Vote (if licensed)

Proposed Timeline of ACIP Presentations

June '21
ACIP



Sept '21
ACIP



October
'21 ACIP

Presentation on:

- **Cost-effectiveness analysis and public health impact**
- **GRADE/EtR for use of PCV15/20 in older adults**

Presentation on:

- Comparison of cost-effectiveness analyses
- GRADE/EtR for use of PCV15/20 in adults with underlying conditions

Vote on
recommendations
for all newly
licensed vaccines